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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,654	11/12/2003	Sylvia A. Norman	GP141-03.UT	8961

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,654	NORMAN ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *7-13, 15-16, 18- 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 32* is/are rejected.

7)☒ Claim(s) *3-6,14,17 and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment

1. Applicant's amendment filed on 10/6/06 is acknowledged.

Status of claims

2. Claims 1-33 are pending.

Claims 1-6,14,17, 20, 22, 23 and 32-33 have been amended.

Claims 1-6, 14, 17, 32 and 33 are under examination as an elected invention.

Claims 7-13, 15-16, 18- 31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected group.

Claim Rejections - 35 USC 101 withdrawn

3. In view of amendments to the claims, the rejection of claims 1-6 and 14 under 35 U.S.C. 101 is withdrawn.

Claim Rejections - 35 USC 112, second paragraph withdrawn

4. In view of amendments to the claims, the rejection of claims , the rejection of claims 1-6, 14, 17, 32 and 33 under 35 U.S.C. 112, second paragraph is withdrawn .

Claim Rejections - 35 USC § 102 maintained

5. The rejection of claims 1 and 32 are under 35 U.S.C. 102(e) as being anticipated by Lee et al (U.S. Patent No. 6,770,479) is maintained.

Applicant states that the sequence disclosed by Lee et al. (SEQ ID NO:4 in US Patent No. 6,770,479) is a 1,710 nucleotide sequence which contains a subsequence identical to at least one of Applicants' target sequences (a 57 nucleotide sequence). That is, the prior art discloses a 1,710 nucleotide sequence that contains a smaller target sequence identified by Applicants. The 1,710 nucleotide sequence of the prior art, however, does not fall in the size range of the claimed oligonucleotides. Thus, nucleotide sequence of Lee et al is not a prior art.

Applicant's arguments filed on 10/6/06 have been fully considered but they are not deemed to be persuasive because applicant is not claiming a composition and kit (i.e., product) comprising a synthetic oligonucleotide consisting of about 20 to about 40 nucleotides that hybridizes specifically to a sequence contained in a B.anthracis target sequence. In the absence of "consisting of" limitation in the claims, Lee et al anticipated the claimed invention.

New Claim Rejections - 35 USC § 112, first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 2 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims are drawn to drawn to a composition and a kit comprising a synthetic oligonucleotide of about 20 to about 40 nucleotides that hybridizes specifically to a sequence contained in a B. anthracis target sequence consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24 or a complementary sequencer RNA equivalent of any one of the target sequences, wherein the synthetic oligonucleotide hybridizes specifically to a pagA target sequence contained in the sequence consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, or SEQ ID NO:24, a complementary sequence, or RNA equivalent of any one of the pagA target sequences

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity

of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

It is noted that given the claims do not define specific hybridization conditions, thus, it is assumed for examination purposes that specific hybridization is hybridization at any stringency across the whole range of stringency conditions wherein any level of specific hybridization takes place since any sequence that hybridizes to SEQ ID NO:21 (SEQ ID NO:1 or 2) or 22 (SEQ ID NO:3 or 4) or 23 (SEQ ID NO: 5 or 6) in fact "is specific for" SEQ ID NO:21or 22 or 23

It is noted that given the unlimited a definition for the term "complementary", wherein the specification specifically teaches that "complementary" means "Complementary" nucleic acids (or "complementarity") refers to a nucleic acid sequence in one strand of nucleic acid, which due to orientation of functional groups, will hybridize, generally via hydrogen bonds, to another nucleic acid sequence on an opposing strand". It is assumed for examination purposes that the term complementary has the art recognized meaning of the term wherein complementary refers to the natural binding of polynucleotides under permissive salt and temperature conditions which includes both partial and complete complementarity (see US Patent No. 5,912,143, col 5, lines 19-32), wherein complementarity of even a single nucleic acid residue is a partial complement and meets the limitations of the claims.

As drawn to the unlimited hybridizing and complementary polynucleotides, since neither

hybridization conditions nor complementary sequences are in any way limited by the claims or by the teaching of the specification the specific hybridization claimed is assumed to be under conditions ranging from very low, or permissive to very high stringency and thus the claimed hybridizing polynucleotides read on polynucleotides that range from those that lack significant complementarity to those that are completely complementary to the claimed polypeptide. Again the term complementary include those that have partial or complete complementarity to SEQ ID NO: 21/22/23/24 and in particular read on those with only two or three nucleic acid residues that are complementary to those found in SEQ ID NO: 21/22/23/24. Thus, complementary polynucleotides include not only the complement, which is completely complementary to the coding sequence of SEQ ID NO: 21/22/23/24 , but also includes a substantial number of species which lack significant complementarity to SEQ ID NO: 21/22/23/24.

One cannot extrapolate the teaching of the specification to the scope of the claims because the specification does not provide teachings or working examples which would provide sufficient guidance to allow one of skill in the art to use the multitude of polynucleotide sequences encompassed by the scope of the claims. Clearly, it would be expected by one of ordinary skill in the art that a substantial number of the hybridizing or complementary polynucleotides encompassed would not be expected that any of the polynucleotides without, substantial complementarity to the polynucleotide SEQ ID NO: 21/22/23/24 which could function as contemplated. Further, the specification does not provide either guidance on or exemplification of how to use the multitude of polynucleotides encompassed by the claims. In view of the above, one of ordinary skill in the art would be forced into undue experimentation to practice the claimed invention.

Remarks

8. Claims 1, 2 and 32 are rejected.

Claims 3-6, 14, 17 and 33 are objected as they depend from a rejected base claim.

Conclusion

9. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER